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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,836	11/21/2003	Yitzhak Zilberman	A328B-USA	1327

24677 7590 10/20/2006

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EXAMINER

SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/718,836	Applicant(s) ZILBERMAN ET AL.	
	Examiner Terri L. Smith	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11-21-03, 2-23-04, 3-5-04</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species:

Embodiment I, drawn to Fig. 35

Embodiment II, drawn to Fig. 36.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic or allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. During a telephone conversation with Malcolm Romano on Thursday, 05 October 2006 and a subsequent voice mail message left by Malcolm Romano on Friday, 06 October 2006 a provisional election was made without traverse to prosecute the invention of Embodiment I, Fig. 35, represented by claims 1–26. Affirmation of this election must be made by Applicant in replying to this Office Action. Claims 27–29 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Claim Objections*

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 20 (duplicate) and 21 have been renumbered to 21 and 22, respectively.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

6. Claims 4 and 6–13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In claim 4, “implantable device” is inferentially included and it cannot be determined if the implantable device is being positively recited or functionally recited. To positively claim the element, it is suggested to first positively recite the element. Otherwise, functional language such as “for” or “adapted to be” should be used.

In claim 6, “electrodes” and “implantable device” are inferentially included.

In claim 10, “implantable device” is inferentially included.

In claim 11, “implantable device” and “distal electrode” are inferentially included.

In claim 13, “implantable device” is inferentially included.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

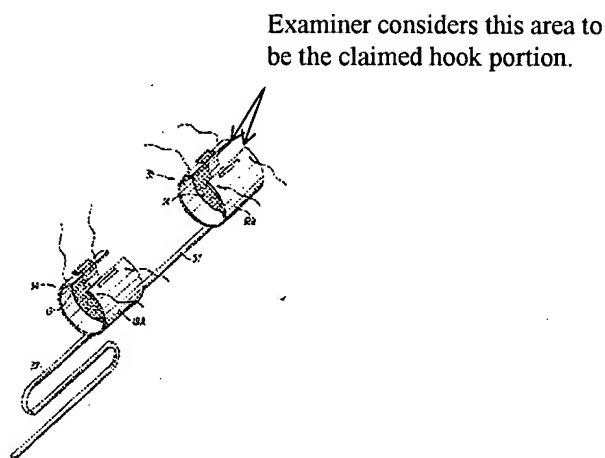
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3–9, 11–14, 16–22 and 24–25 are rejected under 35 U.S.C. 102(e) as being anticipated by Maschino et al., U. S. Patent 6,600,956.

9. Regarding claims 1 and 14, Maschino et al. disclose a placement structure (Figs. 1A, 3, 4A, 5A–5C, and 7A) for facilitating placement of an implantable device having at least two electrodes proximate to neural/muscular tissue, a placement structure comprising/ a method comprising the steps of: (forming) a holder having a hollow cavity formed within that is capable of holding and retaining an implantable device within because the holder elastically expands along its circumference and will stretch to accommodate an implantable device and because the size and dimensions of the implantable device have not been set forth (1A, 2A, 3, 4A–4E, 5A–5C and 7A–7B); (forming) at least one set of elastic wings for capturing neural/muscular tissue (Fig. 3); and wherein holder and wings which comprise a placement structure is primarily formed from a biocompatible plastic (column 5, lines 33–34; column 4, line 43).

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10. With respect to claims 3 and 16, at least one of the wings additionally comprises a hook portion for capturing neural/muscular tissue (claims 3 and 16) (Fig. 3 reproduced and labeled as shown below).



11. Maschino et al. disclose an implantable device is essentially tubular (13 and 14, electrical conductors, which Examiner is interpreting as the tubular implantable device) and a holder is essentially semi-circular in cross section having first and second end plates enclosing a hollow cavity in-between (Fig. 1A), wherein a holder is capable of being suitable for elastically retaining an implantable device because the holder elastically expands along its circumference and will stretch to accommodate an implantable device and because the size and dimensions of the implantable device have not been set forth (claims 4 and 17); the wings of a placement structure have inner and outer surfaces with an inner surfaces of the wings directed toward a holder (Fig. 3) and wherein a structure is suitable for retaining neural/muscular tissue in contact with electrodes of an implantable device (ABSTRACT, line 1) by providing an elastic force from the inner surfaces of the wings toward an implantable device within a holder (column 7, lines 58–62) (claims 5 and 18) and at least one of the wings includes an electrically conductive portion on its

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inner surface that provides an electrically conductive path to a portion of a hollow cavity of a holder (Fig. 3), wherein at least one of the electrodes of an implantable device is capable of being electrically connected to an inner surface of at least one of the wings when an implantable device is inserted within a holder because the wings have conductive strips on the inner surface (Fig. 3) (claims 6 and 19); a conductive portion is formed to minimize eddy currents (claims 7 and 20) (Figs. 1 and 3; column 4, lines 34–36 where it is inherent that the reference current spread is, in its broadest interpretation, an eddy current because an eddy current is a current that runs contrary to the main current); a conductive portion is comb shaped (claims 8 and 21) (Figs. 4D–4E; a conductive portion is formed from serpentine paths (claims 9 and 22) (Fig. 1A; column 4, lines 32–33; column 7, lines 30–32 where Examiner is interpreting the braided or woven material to represent the serpentine paths).

12. Regarding claims 11 and 24, Maschino et al. disclose an implantable device has proximal and distal electrodes (Fig. 3, elements 13 and 14) and a placement structure comprises first and second opposing wings (Fig. 3, elements 34 and 35) and wherein a first electrically conductive path is formed between a proximal portion of a hollow cavity and a first wing (13 and 34) and a second electrically conductive path is formed between a distal portion of a hollow cavity and a second wing (14 and 35), wherein a proximal electrode of an implantable device is capable of being electrically connected to an inner portion of a first wing because the wing elastically expands and will stretch to accommodate an implantable device and because the size and dimensions of the implantable device have not been set forth and the wing has conductive strips on its inner surface (column 9, lines 3–7) and a distal electrode of an implantable device is capable of being electrically connected to an inner portion of a second wing (column 9, lines 3–

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7) when an implantable device is inserted within a holder because the wing elastically expands and will stretch to accommodate an implantable device and because the size and dimensions of the implantable device have not been set forth and the wing has conductive strips on its inner surface.

13. With respect to claims 12 and 25, Maschino et al. disclose a distal portion of a holder includes a boot type structure (Fig. 7A, the structure including elements 99, 104 and 106) having an inner surface capable of holding a distal end of an implantable device because the holder elastically expands and will stretch to accommodate an implantable device and wherein at least a portion of an inner surface of a boot type structure is capable of including electrically conductive paths for providing electrical connection between a distal electrode of an implantable device and a second wing when an implantable device is inserted within a holder because the wings have conductive strips on the inner surface that share a common electrical lead coupled between the wings.

14. Regarding claim 13, Maschino et al. disclose an implantable device has a plurality of sensor/stimulator portions coupled to a plurality of electrode connectors at the outer surface of the implantable device (Fig. 1A, elements 13–15 and 20), a placement structure additionally comprising: a plurality of electrodes distributed within the wings (elements 13–15); a plurality of electrically conductive portions within a holder (column 7, lines 9–13) and a hollow cavity capable of coupling the electrode connectors of an implantable device to the plurality of electrodes because the hollow cavity has conductive strips exposed on the outer surface connected to a lead that would connect with the electrode connectors of the implantable device;



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and wherein a structure is suitable for interfacing to the electrodes to selectively sense signals from the neural/muscular tissue (column 11, lines 17-20).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 2, 10, 15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maschino et al., U.S. Patent 6,600,956.

18. With respect to claims 2 and 15, Maschino et al. disclose the essential features of the claimed invention except for biocompatible plastic is silastic. However, it is well known in the art to use silastic biocompatible plastic for implantable structures to optimize expansion and elasticity of the structure for accommodation of and conformance to the tissue to which it is appropriately attached. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Maschino et al. to include

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silastic biocompatible plastic to maximize cooperation and function between an implantable device and body tissue.

19. Regarding claims 10 and 23, Maschino et al. disclose the essential features of the claimed invention as described in claim 6 above except for two sets of wings. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include two sets of wings, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

***Allowable Subject Matter***

20. Claim 26 is allowed.

***Conclusion***

21. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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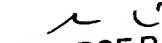
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TLS

October 13, 2006

13 October 2006

  
GEORGE R. EVANISKO  
PRIMARY EXAMINER  
10/14/06